BMJ Paediatrics Open

Innovative continuum of care to promote exclusive breast feeding in Pakistan: protocol of a pilot randomised controlled trial

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To cite: Chaudry ZA, Naz T, Arshad I, *et al*. Innovative continuum of care to promote exclusive breast feeding in Pakistan: protocol of a pilot randomised controlled trial. *BMJ Paediatrics Open* 2024;**8**:e002562. doi:10.1136/bmjpo-2024-002562

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjpo-2024-002562).

Received 8 February 2024
Accepted 16 April 2024

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ABSTRACT

Background Breastmilk being the ideal nutrition from birth to 2 years and beyond has many health benefits for both newborn and mothers. This study will assess the feasibility and acceptability of a continuum of care programme, which is a health facility and community based till 6 months post partum to encourage ideal breastfeeding practices.

Methods and analysis A pilot randomised control trial having two-parallel arms of intervention and control groups was conducted in gynaecology and obstetrics department of Aziz Bhatti Shaheed Teaching Hospital with a community outreach component of 6 months. 50 women between 28 and 32 weeks of gestation fulfilling inclusion criteria will be allocated in 1:1 randomly into intervention and control groups through computer-generated random number generator software. 25 participants in intervention group will receive counselling and training on breast feeding during antenatal visits along with a family member of support by a trained female doctor within the hospital, at birth by a trained nurse and at home for 6 months by a trained lady health worker. It will be supported by reading materials and videos through a mobile phone WhatsApp application. The 25 participants in control group will receive the support already provided within the hospital and at home. The primary outcomes feasibility and acceptability will be determined at 6 months post partum from participants and providers by a semistructured questionnaire. The secondary outcomes are rates of infant early initiation and exclusive breast feeding at 2 weeks, 1, 3 and 6 months, Infant Feeding Attitude at 1 month and Breastfeeding Self-Efficacy at 3 months. Quantitative and qualitative data will be analysed via SPSS software V.20 and thematic analysis, respectively.

Conclusion This pilot randomised controlled trial (RCT) will guide the interventions for the definite RCT.

Ethics and dissemination Approved by institutional ethical committee, informed consent from all participants and results will be disseminated in peer-reviewed journal.

Trial registration number NCT05951868.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Mother's breastmilk is the ideal source of nutrition for newborn till 2 years or beyond, with health benefits for both mother and newborn in form of protection from acute illnesses, chronic diseases and mortality rates.

⇒ Individual support programmes have shown benefits in encouraging mothers ideal breastfeed practices with contextual variability.

WHAT THIS STUDY ADDS

⇒ This pilot randomised controlled trial will assess if a systematic continuum of care programme, extending from hospital during antenatal period to home-based care 6 months post partum within available resources is acceptable and feasible to improve exclusive breast feeding practices.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study will inform an optimised definitive randomised control trial.

⇒ It will also lead to further studies to guide policies and practices for low-resource countries.

BACKGROUND

Undernutrition is related to around 45% of all the deaths in children annually or 2.7 million children dying globally. To encourage the growth, development and survival of infants and children the recommended breastfeeding practices of early initiation within 1 hour, exclusiveness till 6 months, safe complementary solid foods at 6 months with continuation of breast feeding till 2 years and beyond.[1] Breastmilk is the ideal food for infants, offering unmatched safety, purity and antibodies that defend against a variety of childhood diseases. Even in the second year of life, it contributes to about one-third of the child's needs.[2] Each year optimal breast feeding saves 820 000 lives of children less than 5 years of age.[3] Breast feeding for longer duration is also linked to decreased incidence of diabetes mellitus, hyperlipidaemia, obesity, hypertension, myocardial infection, breast and ovarian cancers in mothers.[4–7]

Barriers to Exclusive Breast Feeding (EBF) included low awareness of benefits of breast feeding, cultural practices of prelacteal feeds, myths of insufficient breast milk, colostrum, bitterness of milk and weakness of the mother. Among other barriers are undernutrition of mothers, less birth spacing, mother's occupation, not proper latching or positioning, maternal and child ailments, abnormalities in breasts, and influence of family to start top up feeds.[8–11] Educating mothers on breast feeding makes them more knowledgeable, concerned and prepared with a tendency to improve breast feeding.[12–14] Mother and infant skin-to-skin contact soon after birth are reported by a study of having beneficial effects on breast feeding.[15] Smartphone-based applications have a convincing positive influence on mothers breastfeeding knowledge, self-efficacy and practices.[16] Increased utilisation of antenatal care (ANC), health facility services, skilled attendance at birth by pregnant women were also observed with targeted m-Health interventions.[17] The breastfeeding care plus programme improved perception of breastfeeding self-efficacy in the first 4 months post partum compared with routine care, which favoured competence of mothers and families with breastfeeding exclusiveness and duration.[18] A regular individualised support has also resulted in behavioural change and improved exclusive breastfeeding rates.[14] A multidimensional approach involving mother, her family, healthcare providers working in health facilities and community outreach programmes prelacteal feedings can be reduced by 25% and EBF can be improved by 23%.[11]

As reported in Pakistan Demographic and Health Survey, infant mortality rate is 62 deaths per thousand live births. 86% of pregnant women in Pakistan receive ANC. In 2018, over 28 years, there has been an increase from 13% to 66% in facility-based deliveries. Similarly, 69% of births are attended by a skilled provider. At the age of 0–1 month, 2–3 months and 4–5 months, the infants exclusively breastfed are 56%, 52% and 35%, respectively, with a rapid decline after 3 months.[19 20] With lady health workers (LHWs) within the community acting as a backbone of primary care delivery at village level in place with a mandate to improve child mortality and nutrition but with limited focus on breast feeding[21] gives an opportunity to strengthen and use the existing resources in low-income to middle-income countries and develop a coordinated continuum of care programme from pregnancy to 6 months postpartum to improve ideal breastfeeding practices.

When relevant interventions are delivered adequately, practices and responsiveness to breast feeding can improve rapidly. When interventions are concurrently implemented via several channels only then better outcomes are achievable.[22–24]

Rationale of the study

There has been constant improvement in utilisation of maternity services in healthcare facilities from skilled health providers. There is also an improvement in communication and excess to information with the use of cell phone technology in almost every household via telephone call, text messages and WhatsApp application. In parallel population of Pakistan, a developing country is on a steep rise which brings along poverty and food insecurities. In order to secure health and well-being of both mother and newborn in developing countries, it is inevitable to educate, encourage, support and convince mother to follow ideal breastfeeding practices to improve survival and health of children with practices which comes at a minimal cost but huge benefits. Keeping in view the best practices and all the available opportunities, a continuum of care programme for breast feeding from health facilities with extension to the community where mothers reside, using available resources in a systematic and continuous manner to educate, support and motivate mother and her family is inevitable.

This study will assess the feasibility and acceptability of continuum of care programme in parallel to the already existing support system till 6 months post partum which is both health facility and community based to encourage early initiation, exclusive breast feeding till 6 months and conviction of continuation of breast feeding till 2 years and beyond. The study will inform a definitive randomised controlled trial (RCT).

Study design

Two-armed, parallel groups, pilot RCT with random allocation of as 1:1 ratio in the intervention and control group (figure 1). Study schedule is according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement 2013.

Study setting

Outdoor patient department (OPD) of gynaecology and obstetrics department of government, Aziz Bhatti Shaheed Teaching Hospital (ABSTH) Gujrat, Punjab Pakistan.

Study participants

Pregnant women attending prenatal clinic, meeting inclusion and exclusion criteria will be invited verbally to participate in the study. Enrolment will only be done with their informed consent.

Inclusion criteria

Age over 18 years, 28–32 weeks gestation, nulliparous or multiparous, communicates verbally in Urdu or Punjabi languages, intends to deliver at ABSTH, Gujrat and has excess to smart phone with WhatsApp application.

Exclusion criteria

LHW not appointed in mother's community, not able to articulate, medical conditions or illness hindering in understanding or breast feeding.

Sample size

There is no definitive rule or formula for calculating the optimal sample size for a pilot test, but some general principles should be taken into consideration. A sample size

	Study Period										
	Enrolment	**Allocation**	**Post Allocation**								**Close Out**
Time points	After 28 weeks of gestation		>28 weeks gestation	At birth	1st week	2nd week	1st month	3rd month	4th month	6th month	7th month
Eligibility screen	×										
Informed consent	×										
Allocation		×									
Interventions											
Continuum of support activities			—	—	—	—	—	—	—	—	
Assessments											
Demographic profile	×										
1.Infant feeding status				×	×						
2.Iowa Infant Feeding Attitude Scale (IIFAS)						×					
3.Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF)								×			
1.Feasibility of interventions											×
2.Acceptability of interventions											×
3. Extent to which the intervention is implemented as intended											×

Figure 1 SPIRIT schedule of enrolment, interventions and assessments. SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.

of minimum 12 participants in one arm for a pilot study is considered as a rule of thumb. A sample size range of 24–60 participants is derived from general guidance found in the literature on pilot and feasibility studies and a practical guideline for ensuring enough participants to assess feasibility and preliminary outcomes without the expectation of statistical power for efficacy or effectiveness analyses.[25–27] Keeping in consideration 20% attrition rate of the pilot sample,[28] 50 participants in total will be considered for the study.

Recruitment

Recruitment will be done on 3 days a week of routine OPD of gynaecology and obstetrics department teaching unit of ABSTH based on inclusion and exclusion criteria. Informed consent in Urdu or Punjabi language from all participants agreed to participate in the study up till 6 months postpartum will be taken.

Randomisation, allocation and blinding

Simple randomisation, the randomisation sequence will be computer generated using random number generator software.

The sequence of 25 computer-generated numbers will be randomly allocated into intervention group. The remaining 25 will be included in the control group.

The allocation sequence will only be known by the principal researcher. The care provider and outcome assessors will be blinded from allocation sequences and intervention or control groups.

Intervention process

Preintervention trainings

Before the intervention, training of caregivers involved in enrolment and sending invitations to mothers for counselling, female doctor counselling and training mothers on breast feeding, nurse involved in counselling and training right after delivery, LHWs in community

and outcomes data collectors will be done by principal researcher and a senior trained gynaecologist and obstetrician.

Hospital-based intervention

1. Participants in intervention group will be invited telephonically by a lady health visitor to come to ABSTH for breastfeeding counselling sessions and antenatal visit on a particular day with a female family member considered as her support (to assist and support mother at home).
2. Counselling by a trained female doctor in groups of 5–7 participant mothers with their family member for almost 40 min on ideal breastfeeding practices (benefits, latching, positions, myths, difficulties and discussion).
3. During first antenatal visits and at the time of discharge from the hospital after delivery, a booklet for participants and video recordings having similar content to counselling will be sent via WhatsApp on the cell number provided by participants.
4. After delivery in recovery room or ward, a trained nurse will assist in early initiation of breastfeed, hands on train on latching technique, feeding positions and emphasise on exclusive breast feeding till 6 months.

Community-based (at-home) intervention

After delivery in hospital and discharge when mother reaches home:

1. Trained LHW of the participant's community will visit regularly on the following dates 0, 1, 2 weeks and 1, 3, 4 and 6 months after delivery to assist and support breast feeding (table 1).

Control group

The control group will receive the support already provided within the hospital by the staff and nurses and at home by community health workers and family.

Follow-up will be after 2 weeks, 1, 3 and 6 months of delivery as in intervention group to determine the outcomes of the routine care.

OUTCOME MEASURES

Primary outcomes

Feasibility of interventions

At seventh months after delivery, with a semistructured questionnaire participants and care provider's feasibility, practicality of interventions will be determined.

Acceptability of interventions

At seventh month after delivery, with a semistructured questionnaire participants and care provider's satisfaction, comfort and willingness to continue with the intervention will be determined.

Extent to which the intervention is implemented as intended

On completion of study, structured Performa's and monitoring tools embedded within the pilot RCT will assess feasibility of implementation and operational procedures of the interventions, training and supervision procedures. Including records, providers and participant's engagement and feedback.

The semistructured questionnaires expert reviewed and pilot tested will determine both feasibility and acceptability of the intervention and the trial procedures (online supplemental files 1,2).

Secondary outcome measures

Infant feeding status

A standard questionnaire using WHO indicators translated into local language for assessing breastfeeding initiation and exclusive breastfeeding rates at 2 weeks, 1, 3 and 6 months with intentions beyond 6 months.[29]

Iowa Infant Feeding Attitude Scale

A standard adopted 17 questions scale form translated into Urdu language will be used for telephonic inquiry from both intervention and control group participants to determine attitude towards breast feeding after 1 months of delivery.[30]

Breastfeeding Self-Efficacy Scale-Short Form

A standard adopted 14-item scale translated into Urdu language will be used for telephonic inquiry from both intervention and control group participants to determine self-efficacy in breast feeding after 3 months of delivery (online supplemental file 3).[31]

Data collection

Demographic information will be collected from the participants at the time of enrolment after informed consent and fulfilment of inclusion criteria.

Follow-up data collection of all primary outcomes will be done telephonically and directly through a pretested semistructured questionnaire translated into Urdu from all participants and providers (including those discontinuing or deviating from protocol) at end of the study. The secondary outcomes data will also be collected telephonically regarding, infant feeding status, future feeding intensions, Breastfeeding Self-Efficacy, Attitude towards breast feeding at 1, 3 and 6 months post partum by different providers for intervention and control groups through standard measuring questionnaire tools. Any other form of breastfeeding support given will be noted. Follow-up of participants will continue till 6 months postpartum (figure 2).

Data management plan

Data containing consent, personal information of participants, steps of subsequent interventions and the outcomes data collected by the providers will be taken in hard form and softcopy filed in central record and personal computer, respectively, by principal researcher.

Data analysis

All collected data will be entered into SPSS V.20 statistical software for analysis. Descriptive statistics will summarise

Table 1 Continuum of care intervention content and activities

	Content	Methodology	Material
1	Counselling of pregnant women above 28 weeks of gestation on: 1. Mother's nutrition in pregnancy and during lactation. 2. Recommended breastfeeding practices and weaning. 3. Benefits of breast feeding for mother and newborn 4. Latching and feeding positioning after normal and caesarian delivery 5. Ways to express milk manually 6. Myths and common problems with solutions in feeding of newborn 7. Discussion and Question & Answer session	The training will be done in groups of 5–7 pregnant women along with a female family member considered as a support by mother. Session conducted by a trained female doctor in maternal and perinatal care. Two sessions lasting between 40 and 60 min within the hospital setting. The sessions will be via direct contact with group of participants in a separate room within the hospital	1. PowerPoint/verbal/ onboard or pictorial presentation 2. Baby doll 3. videos
2	Hands on training to establish breast feeding after delivery. training on breast feeding within 1 hour, rooming in, latching and breastfeeding positions and ideal feeding practices for 2 years. .	Establish breast feeding within 1 hour of delivery and helping in various positions of breast feeding by a trained nurse and reemphasize on already counselled ideal breastfeeding practices.	Hands of training and verbal instructions.
3	Take home reading booklet and WhatsApp video recordings Content similar to counselling material. (Mothers' nutrition, ideal breast feeding practices, benefits, myths, common breastfeeding problems, solutions, positioning and expression of milk techniques)	Pamphlet/Booklet (soft copy sent on WhatsApp of participant) after 1st counselling session in hospital and after delivery by LHV 2, Lectures/training video sent on participants WhatsApp on day of 1st counselling in hospital and after delivery	Booklet and three short videos recorded by a female doctor in local language Urdu. .
4	Catchment areas LHWs home visits to delivered mothers from birth till 6 months postpartum Content similar to counselling material.	Counselling at birth, at week 1, week 2, 1st, 3rd, 4th and 6th month after delivery to assist and support mother through various stages of newborn breast feeding and answer arising queries. Also, re-emphasize already learnt information and encourage family's support for mother to exclusive breastfeed till 6 months and continue breastfeed till 2 years and even beyond. Tick the checklist on each visit sign and send via WhatsApp to central record with a pictorial evidence of each visit.	Booklet/training material and checklists.
5	Follow-up to inquire on primary and secondary outcomes of the study of both intervention and control group	Telephonically from participants and caregivers at various stages of study by different data collectors for both groups.	Semistructured questionnaire

LHV, lady health visitor; LHW, lady health worker.

demographic statistics of participants with number of women assessed for enrolment, excluded as per set criteria, consented to participate and lost to follow-up.

To compare the outcomes of intervention and control group participants, descriptive statistics will be used to evaluate the primary and secondary outcomes of pilot RCT.

Qualitative data from questionnaire will be transcribed, content will be analysed, coded to identify themes.

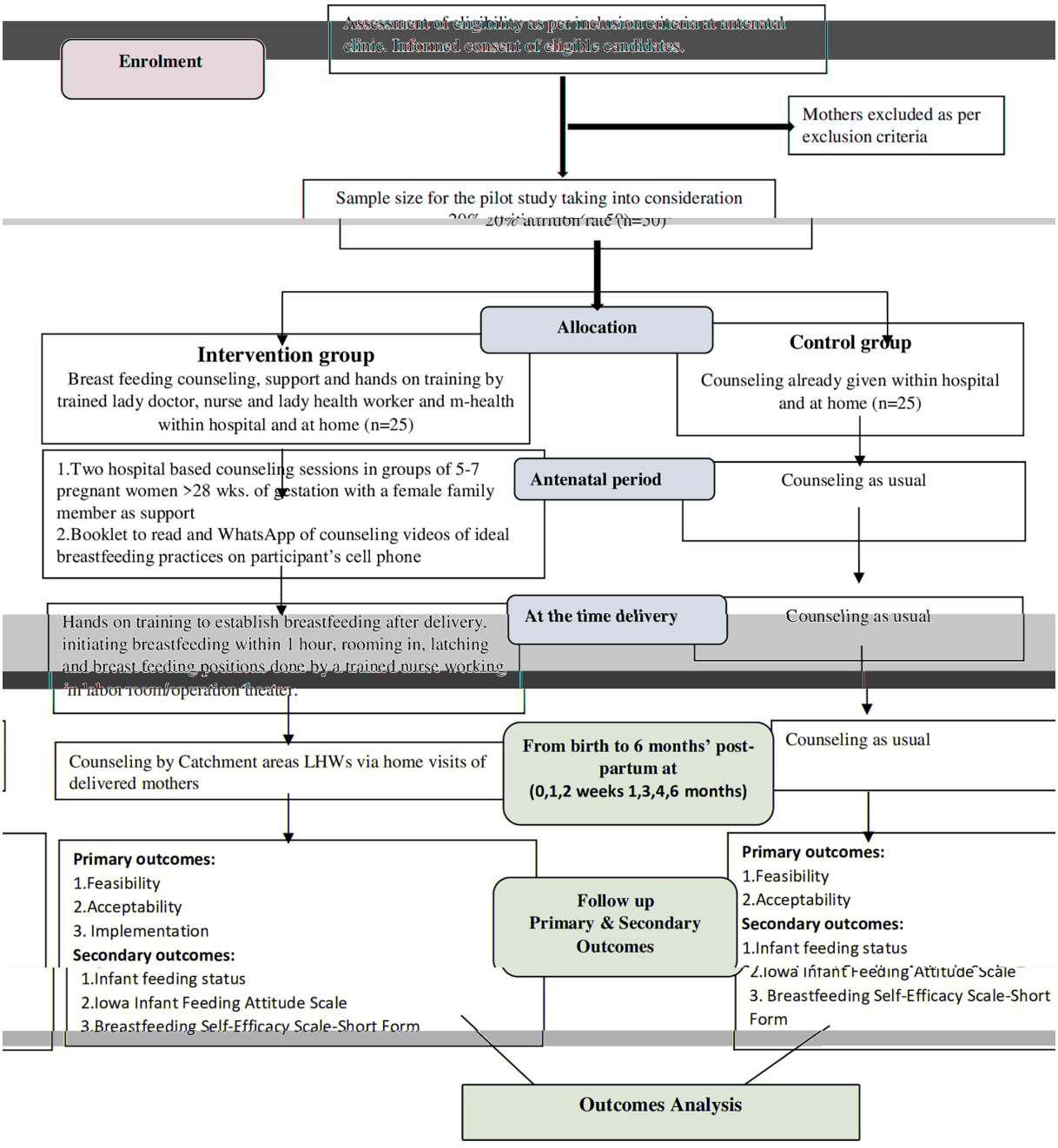

Figure 2 Flow diagram of the study.

Data monitoring

Due to minimal risk, data monitoring committee is not required. All queries will be responded appropriately. Adverse event will be reported to the ethics committee and intervention can be discontinued.

Study reporting guidelines

This protocol of RCT is reported by the SPIRIT guidelines (online supplemental file 4).

Patient and public involvement

The study materials, interventions, conduct and data collection mechanism were designed using patient public involvement in group and individual discussions to improve the acceptability of the study.

DISCUSSION

The pilot study covers all the possible care mechanisms at various stages of mother and the newborn to enable mothers to adopt ideal breastfeeding practices keeping in consideration culture, human resource and financial constraints in a developing country. Many studies have been carried out on the individual components of various support mechanisms but limited work has been done on systematic and continuum of care within low-income and middle-income countries.[32 33] Various components of the continuum of care programme may act in synergy or a certain component may act as a trigger for mother to opt ideal breastfeeding practices. If a component is missed at one stage, care can still be offered at the next stage.

Studies have encouraged development of such comprehensive programmes.[34] With improved health facilities, excess to maternity services, utilisation of maternal and child health services, excess to android cell phones and internet services, there lies an opportunity to test a multi component, continuous support programme for mothers to breastfeed.[35 36] With evolving nuclear family system, poor emphasis on counselling and training from healthcare providers, misconceptions and myths within communities, lack of support from family and relatives has undermined benefits of breastmilk and timely breast feeding.[37 38] These can only be addressed by a continuum care programme for the mother from the time of pregnancy through her breastfeeding period, as an ongoing reinforcement from all elements such as; health facility, healthcare providers, health workers within communities and family members she encounters during this period.

The strength of this study is that the interventions are based on existing resources, workload and cultural acceptability, convenient for both participants and providers in improving outcomes. The inclusion of secondary outcomes provides further insights into mother's attitude, self-efficacy and practices towards breast feeding. Inputs from all providers and participants will be taken to understand gaps, draw conclusions from various perspectives resulting in a refined definitive study.

The study comes with a few limitations; shortage in human resources in health, limited excess of mothers to health facility, no excess to mobiles, LHWs overburdened with limited incentives alongside variable mobility, security, cultural and social barriers.

CONCLUSION

The study outcomes will guide the interventions for a definite RCT.

Acknowledgements We are thankful for the support and facilitation provided by the District Health Department Gujrat & Department of Gynecology & Obstetric, ABSTH Gujrat, Punjab, Pakistan.

Contributors ZAC: conceptualisation, methodology, resources, project administration, data curation, writing–original draft preparation. TN: investigation, project administration, resources. IA: investigation. AZ: investigation. MJ: investigation, resources. SS: supervision, conceptualisation, methodology.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests No, there are no competing interests.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Institutional Review Board (IRB)/ethical committee of NSMC and ABSTH, Reference # 24-IRB/2021. Informed consent was taken from participants. Authorised providers will have access to data under obligation of secrecy. Any modification in protocol will be reported to ethical committee, trial registry, participants, providers and journal. All reports of study results will be anonymous and results will be disseminated in peer-reviewed journal. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. Not applicable.

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